AMENDMENTS TO THE CLAIMS

Claim 1 (Currently Amended): A thermal adhesion granulation process for preparing direct tabletting formulations or aids, comprising the step of subjecting all or part of a mixture comprising:

(a) from about 5 to about 99 % by weight of one or more diluent excipients and/or from 0 to about 99% by weight of a pharmaceutically-active ingredient;

(b) from about 1 to about 95 % by weight of a binder excipient; and optionally with,

(c) from 0 to about 10% by weight of a disintegrant excipient;

to heating at a temperature range of from about 30 to about 130°C under the condition of from about 0.1 to about 20% initial moisture content [~~and/~~]or from about 0.1 to about 20% initial content of a pharmaceutically-acceptable organic solvent in a closed system with mixing [~~by tumble rotation~~] until granules form.

Claim 2 (Original): A process as defined in claim 1, wherein the temperature range is from about 40 to about 110°C.

Claim 3 (Original): A process as defined in claim 1, wherein the temperature range is from about 60 to about 105°C.

Claim 4 (Original): A process as defined in claim 1, wherein the initial moisture content is from about 2 to about 15%.

Claim 5 (Original): A process as defined in claim 1, wherein the initial moisture content is from about 4 to about 10%.

Claim 6 (Original): A process as defined in claim 1, wherein the initial organic solvent content is from about 0.1 to about 10%.

Claim 7 (Original): A process as defined in claim 1, where the initial organic solvent content is from about. 0.5 to about 5%.

Claim 8 (Original): A process as defined in claim 1, wherein the diluent excipient is powdered cellulose, microcrystalline cellulose, lactose, starch, or dibasic calcium phosphate.

Claim 9 (Original): A process as defined in claim 1, wherein the pharmaceutically-active ingredient is acetaminophen or ascorbic acid.

Claim 10 (Original): A process as defined in claim 1, wherein the binder excipient is soluble polyvinyl pyrrolidone or hydroxypropylcellulose.

Claim 11 (Original): A process as defined in claim 1, wherein the disintegrant excipient is crospovidone, sodium starch glycolate, reticulated carboxymethylcellulose, or low-substituted hydroxypropylcellulose.

Claim 12 (Original): A process as defined in claim 1, wherein the diluent excipient is microcrystalline cellulose.

Claim 13 (Previously Amended): A process as defined in claim 12, wherein about 90% of the microcrystalline cellulose particles are in the particle size range from about 1 μm to about 125 μm, and the average particle size of the microcrystalline cellulose particles is from about 10 μm to about 70 μm.

Claim 14 (Original): A process as defined in claim 1, wherein the binder excipient is soluble polyvinyl pyrrolidone.

Claim 15 (Original): A process as defined in claim 14, wherein the soluble polyvinyl pyrrolidone has a K value of from about 12 to about 120.

Claim 16 (Original): A process as defined in claim 14, wherein the soluble polyvinyl pyrrolidone has a K value of from about 20 to about 95.

Claim 17 (Original): A process as defined in claim 14, wherein the soluble polyvinyl pyrrolidone has a K value of from about 25 to about 35.

Claim 18 (Previously Amended): A process as defined in claim 1, wherein the binder excipient further contains from 0 to about 10% by weight with respect to the binder of an anticaking agent.

Claim 19 (Previously Amended): A process as defined in claim 18, wherein the binder excipient contains from about 0.01 to about 10% by weight with respect to the binder of an anticaking agent.

Claim 20 (Previously Amended): A process as defined in claim 18, wherein the binder excipient contains from about 2 to about 4% by weight with respect to the binder of an anticaking agent.

Claim 21 (Original): A process as defined in claim 18, wherein the anticaking agent is dibasic calcium phosphate anhydrous.

Claim 22 (Previously Amended): A product of the process of claim 1.

Claim 23 (Cancelled)

Claim 24 (Cancelled)

Claim 25 (Previously Added): A tablet which comprises a product as defined in claim 22.

Claim 26 (Cancelled)

Claim 27 (Cancelled)

Claim 28 (Previously added): A capsule which comprises a product as defined in claim 22.

Claim 29 (Cancelled)

Claim 30 (Cancelled)

Claim 31 (Previously Added): A pellet which comprises a product as defined in claim 22.

Claim 32 (Cancelled)

Claim 33 (Cancelled)

Claim 34 (Currently Amended): A thermal adhesion granulation process, which comprises:

dry-blending binder excipient, one or more diluent excipients, and a pharmaceutically-active ingredient;

adding water and/or a pharmaceutically-acceptable organic solvent to the dry-blended mixture; and

heating at a temperature range from about 30°C to about 130°C with mixing in a closed system until granules form, wherein:

the binder excipient is from about 1% to about 95% by weight,

the one or more diluent excipients are from about 5% to about 99% by weight,

the pharmaceutically-active ingredient is from 0% to about 99% by weight, and

the water [~~and~~/]or the pharmaceutically-acceptable organic solvent is from about 0.1% to about 20% content before heating.

Claim 35 (Previously Added): The process of claim 34, wherein the mixing is by tumble rotation.

Claim 36 (Previously Added): A process as defined in claim 34, wherein the temperature range is from about 40 to about 110°C.

Claim 37 (Previously Added): A process as defined in claim 34, wherein the temperature range is from about 60 to about 105°C.

Claim 38 (Currently Amended): A process as defined in claim 34, wherein the initial water ~~moisture~~ content is from about 2 to about 15%.

Claim 39 (Currently Amended): A process as defined in claim 34, wherein the initial water ~~moisture~~ content is from about 4 to about 10%.

Claim 40 (Previously Added): A process as defined in claim 34, wherein the initial organic solvent content is from about 0.1 to about 10%.

Claim 41 (Previously Added): A process as defined in claim 34, where the initial organic solvent content is from about 0.5 to about 5%.

Claim 42 (Previously Added): A process as defined in claim 34, wherein the diluent excipient is powdered cellulose, microcrystalline cellulose, lactose, starch, or dibasic calcium phosphate.

Claim 43 (Previously Added): A process as defined in claim 34, wherein the pharmaceutically-active ingredient is acetaminophen or ascorbic acid.

Claim 44 (Previously Added): A process as defined in claim 34, wherein the binder excipient is soluble polyvinyl pyrrolidone or hydroxypropylcellulose.

Claim 45 (Previously Added): The process of claim 34, wherein a disintegrant excipient is included in the dry-blending step.

Claim 46 (Previously Added): A process as defined in claim 45, wherein the disintegrant excipient is crospovidone, sodium starch glycolate, reticulated carboxymethylcellulose, or low-substituted hydroxypropylcellulose.

Claim 47 (Previously Added): A process as defined in claim 34, wherein the diluent excipient is microcrystalline cellulose.

Claim 48 (Previously Added): A process as defined in claim 47, wherein about 90% of the microcrystalline cellulose particles are in the range from about 1 μm to about 125 μm, and the average particle size of the microcrystalline cellulose particles is from about 10 μm to about 70 μm.

Claim 49 (Previously Added): A process as defined in claim 34, wherein the binder excipient is soluble polyvinyl pyrrolidone.

Claim 50 (Previously Added): A process as defined in claim 49, wherein the soluble polyvinyl pyrrolidone has a K value of from about 12 to about 120.

Claim 51 (Previously Added): A process as defined in claim 49, wherein the soluble polyvinyl pyrrolidone has a K value of from about 20 to about 95.

Claim 52 (Previously Added): A process as defined in claim 49, wherein the soluble polyvinyl pyrrolidone has a K value of from about 25 to about 35.

Claim 53 (Previously Added): A process as defined in claim 34, wherein the binder excipient further contains from 0 to about 10% by weight with respect to the binder of an anticaking agent.

Claim 54 (Previously Added): A process as defined in claim 53, wherein the binder excipient contains from about 0.01 to about 10% by weight with respect to the binder of an anticaking agent.

Claim 55 (Previously Added): A process as defined in claim 53, wherein the binder excipient contains from about 2 to about 4% by weight with respect to the binder of an anticaking agent.

Claim 56 (Previously Added): A product prepared by the process of claim 34.

Claim 57 (Previously Added): A tablet comprising the product of claim 56.

Claim 58 (Previously Added): A capsule comprising the product of claim 56.

Claim 59 (Previously Added): A pellet comprising the product of claim 56.

Claim 60 (Previously Added): The process of claim 1, wherein the mixing is by tumble rotation.

Claim 61 (Currently Amended): A method of making a finely divided powder mixture comprising polyvinyl pyrrolidone, which comprises mixing with the composition dibasic calcium phosphate anhydrous as an anticaking agent in an amount of about 0.01% to about 10% by weight with respect to the polyvinyl pyrrolidone.

Claim 62 (Cancelled)

Claim 63 (New): A finely divided powder mixture prepared by the method of claim 61.